REMARKS

Claims 1-27 are pending. Claims 1-6 and 13-27 are withdrawn from consideration in the present application. Claims 8 and 10-12 are canceled herein without prejudice. Claims 7 and 9 are amended herein to more clearly set forth aspects of the invention. New claims 28 and 29 are presented herein. Accordingly, amended claims 7 and 9 and new claims 28 and 29 are under consideration.

Any amendment, however, is not to be construed as abandonment of any subject matter of the originally filed application. Accordingly, it is to be understood that Applicant reserves the right to reintroduce subject matter deleted from the application by the foregoing amendments and to file one or more divisional, continuation, and/or continuation in part applications directed to such subject matter.

Support for the amendments to the claims is found throughout the specification and in the original claims. Specifically, support for the amendment to claim 7 is presented, for example, in original claim 12 and at page 2, lines 25-27 and in Example 3 of the specification. Claim 9 is amended to correct dependency recited therein. No issue of new matter is introduced by the amendments to the claims.

Support for new claims 28 and 29 is found throughout the specification and in the original claims. Specifically, support for new claim 28 is found, for example, at page 6, lines 16-27. Support for new claim 29 is found, for example, at page 2, line 28 through to page 3, line 22. No issue of new matter is introduced by the amendments to the claims.

Applicant acknowledges the Examiner's assertions regarding claims 7-12, which are viewed as free of the prior art. It is believed that the instant claims are also free of the prior art.

Information Disclosure Statement

For the Examiner's edification, the WO 02/04508 application entered the United States national phase and was published in English as United States Patent Application Publication No. 2002-0142003. United States Publication No. 2002-0142003 is, therefore, an essentially equivalent document to that of WO 02/04508, but is presented in English. In that United States Publication No. 2002-0142003 has already been submitted for the consideration of the Examiner as reference AA of the Information Disclosure Statement filed on July 18, 2006, Applicant

believes that the necessary steps have been taken to bring the subject matter of the WO 02/04508 application to the Examiner's attention.

Specification

The Specification is amended herein to correct typographical errors. It is noteworthy that some of the typographical errors identified in the corresponding published application were introduced by the United States Patent and Trademark Office, as these errors were not present in the application as originally filed. Applicant has endeavored to indicate which of the amendments to the specification were necessitated by Patent Office error and which were present in the as filed application. Irrespective of the source of the typographical error, no issue of new matter is introduced by the amendments to the specification.

Applicant believes that the trademarks indicated throughout specification are properly designated by appropriate trademark symbols and capitalized as suggested by the Examiner. No issue of new matter is introduced by these amendments to the specification.

Rejections under 35 USC § 112

Claims 8-9 and 12 are rejected under 35 USC § 112, second paragraph, for alleged indefiniteness. Claims 8 and 12 are canceled herein, thereby obviating any rejection of these claims. Claim 9 is amended herein to depend from claim 7, which does not recite any of the allegedly indefinite language of claims 8 or 12. Reconsideration and withdrawal of the rejection of claim 9 under 35 USC § 112, second paragraph, is, therefore, deferentially requested.

Claims 7-12 are rejected under 35 U.S.C. § 112, first paragraph, for an alleged lack of enablement. Claims 8 and 10-12 are canceled herein, thereby obviating any rejection of these claims. Claim 7 is amended herein to clarify aspects of the claim. More specifically, instant claim 7 is directed to a method for the treatment of ovarian cancer comprising administering a therapeutically effective amount of an antibody which specifically interacts with a CDCP1 polypeptide comprising or consisting of the amino acid sequence of SEQ ID NO: 1 or residues 30-667 of SEQ ID NO: 1. In view of the support presented in the specification for the claimed method and additional corroborative evidence presented in Dr. Mason's Declaration, Applicant asserts that the instant claims are enabled. That being the case, the rejection of claims 7-12 under 35 U.S.C. § 112, first paragraph, is traversed.

It is noteworthy that the present application offers the first disclosure that identifies a positive correlation between CDCP1 over-expression and ovarian cancer tissue. The positive correlation is demonstrated by mRNA over-expression data, as presented in Example 3, and immunohistochemistry data, as presented in Example 4 of the specification. As such, the instant application provides a new target for ovarian cancer treatment. Dr. Mason's Declaration further corroborates the link between CDCP1 over-expression and the presence of ovarian cancer cells. See also Exhibit B. Based on this discovery, the present invention is directed to a new and credible utility for a method of using an antibody directed against CDCP1, a previously unidentified target in ovarian cancer. Accordingly, Applicant asserts that a claim directed to a method of treatment for ovarian cancer which targets cells that over-express CDCP1 using an antibody which is immunospecific for CDCP1 is commensurate in scope with Applicant's contribution to the art.

Responsive to the Examiner's assertions regarding factors to be considered in determining whether a disclosure meets the enablement requirement, Applicant asserts that the present specification, especially when considered in conjunction with Dr. Mason's Declaration, is enabling for the instant claims. On the basis of the experimental results presented in the specification and the supporting Declaration and complementary data presented in Exhibit B, Applicant asserts that a skilled practitioner would understand and readily believe that an antibody specific for CDCP1 would target the CDCP1 present on ovarian cancerous cells since CDCP1 expression is increased in such cells. Moreover, the making and testing of antibodies for the claimed method, while requiring some experimentation by a skilled artisan, does not require undue experimentation. The skilled artisan can readily make and test anti-CDCP1 antibodies using the teachings presented in the specification and their own knowledge and skills.

In particular, the specification teaches:

(i) techniques for the production of antibodies that will immunospecifically bind an antigen in paragraphs [0014] and [0034] to [0038] of the published application;

(ii) antibody-drug conjugation techniques and details regarding the delivery of therapeutic moieties to target cancerous cells using an antibody conjugated to such a moiety; multiple references are cited relating to this issue in paragraphs [0018] to [0019] of the published application, which

body of evidence attests to the fact that antibody-targeted delivery of therapeutic moieties conjugated thereto is well accepted in the art; and

(iii) the preparation of pharmaceutical compositions, as is well established in the art, and methods of determining the correct dosage and routes of administration in paragraphs [0075] to [0096] of the published application.

In view of the fact that claim 7 has been amended to be directed to an antibody, rather than an agent, and on the basis of the data presented in the specification and the supporting Declaration and data presented in Exhibit B, it would be entirely acceptable and credible to the skilled person that an antibody specific for CDCP1 would target the CDCP1 present on cancerous cells. Furthermore, the skilled practitioner would be able, based on the teachings within the specification, to make and test such an antibody without undue experimentation.

Responsive to the Examiner's remarks concerning "whether binding and/or internalization of the antibody/polypeptide complex leads to cell death", Applicant respectfully directs the Examiner's attention to Dr. Mason's Declaration wherein he states that an antibody targeting CDCP1 on ovarian tumors could 'provide a therapy, either through recruitment of immune effector mechanisms, modulation of CDCP1 function or via a toxin conjugated antibody. Any combination of these mechanisms is also possible.' In keeping with Dr. Mason's statements, a skilled practitioner would appreciate that any CDCP1 antibody isolated may internalize, recruit complement to cause cell lysis, recruit effector cells to cause target cell killing, or may exhibit a combination of these effects. The skilled person would also realize upon isolating an antibody specific for CDCP1 that if the antibody can be internalized, it is a candidate for conjugation to a drug.

The Examiner's remarks relating to Ezzell (J. NIH Res., 1995, 7:46-49); Forni et al. (Cancer Research, 2000, 60:2571-2575); Donnelly (Nature Medicine, 2003, 9:1354-1356); De Gruijl et al. (Nature Medicine, 1999, 5:1124-1125); Chatterjee et al. (Cancer Immunol. Immunother., 1994, 38:75-82); Bodey et al. (Anticancer Research, 2000, 20:2665-2676); Lee et al. (J. Immunol., 1999, 163:6292-6300); Rudikoff et al. (Proc. Natl. Acad. Sci. USA, 1982, 79:1979-1983); Burgess et al. (J. Cell Biol., 1990, 111:2129-2138); Lazar et al. (Molec. and Cell. Biol., 1988, 8:1247-1252); Schwartz et al. (Proc. Natl. Acad. Sci. USA, 1987, 84:6408-6411); Lin et al. (Biochemistry USA, 1975, 14:1559-1563) are noted. It is, however, believed that the

amendments to the claims limit the applicability of the above-indicated references with respect to the instant claims. Accordingly, Applicant reserves the right to address each of these references at a later stage in prosecution, should these references be re-asserted in connection with the instant claims.

In view of the amendments to the claims and the arguments presented herein and the assertions presented in Dr. Mason's Declaration, the rejection of claims 7-12 under 35 U.S.C. § 112, first paragraph, is respectfully traversed. In light of the above, reconsideration and withdrawal of this rejection are, therefore, respectfully requested.

Fees

No additional fees are believed to be necessitated by this amendment. However, should this be an error, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment or to credit any overpayment.

Conclusion

It is submitted, therefore, that the claims are in condition for allowance. No new matter has been introduced. From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited. In the event that there are any questions concerning this amendment, or application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of this application may be expedited.

Respectfully submitted,

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Enclosures: Petition for a One Month Extension of Time
Dr. Mason's Declaration
Exhibits A and B